Enclosed please find follow-up questions from the Institute of Medicine Committee to Assess the Science Base for Harm Reduction from Tobacco. A hard copy of this communication is being sent by Federal Express. We appreciate the material you have supplied already and find ourselves, of course, with more questions. Some of these are very specific and others are more conceptual.

1. What evidence is there to conclude that there is or is not a threshold effect for cancer, heart disease, adverse reproductive effects or lung disease caused by exposure to tobacco or tobacco smoke, and what is the threshold level, if it exists.

2. Do the filters in your cigarettes, including reduced-risk products under test-market or development, contain fibers? If so, can these fibers become airborne in the smoke inhaled by smokers? If so, to what extent does this occur? What is your estimate of the potential risk to human health from these fibers?

3. What is the effect of removing a component or components of tobacco on the qualitative and quantitative composition of the new species of smoke? What is the empirical evidence that such alteration would be associated with reduced or altered disease incidence in humans?

4. What are the criteria that should be used to assert that a specific form of tobacco or tobacco product is less harmful than others? What biomarkers should be used to assess the criteria?

5. What is the appropriate comparison product for reduced-risk products? A Kentucky reference cigarette? The leading product as assessed by market share? The lowest-risk product currently available? Each individual smokers brand at time of switching to the new product? Each individual smokers dominant brand of his/her smoking history?

6. What endpoints would you recommend for assessing harm reduction through use of reduced risk products or by decreasing consumption of existing products via use of nicotine replacement therapies or other pharmaceutical products?

7. What clinical exposure data in humans do you feel is important or even necessary for evaluation of a new tobacco product (smoked and smokeless) before it is marketed? Please be specific with respect to number of subjects, length of use, biomarkers measured and tests conducted.

8. If a goal is to develop a reduced-risk product that is still attractive to smokers who wish to continue smoking, what research agenda would you recommend? What do you need to know to accomplish this that you do not know already? Consider same question for smokeless tobacco products and comment on the possibility suggested by Swedish Snus that taste can be maintained while risk is minimized.

9. What is the extent of your plans for internal or external activities in supporting health outcomes studies for your products? Particularly, do you support or plan to support epidemiological or related investigations?

10. What might be the best mechanisms to foster collaborative studies between tobacco industry, university, and other scientists?

Source: https://www.industrydocuments.ucsf.edu/docs/gglx0001

11. What roles should various sectors (e.g. industry, academia, government, foundations) play in the design, funding, oversight, reporting, and modification of post-marketing surveillance of newly introduced reduced risk products?

12. What is your thinking on the design of a population-based study to assess the effects of the introduction of a reduced-risk product on risk perception of tobacco use and on tobacco initiation, cessation, or relapse?

Please indicate supporting references where appropriate. If these are not easily obtainable from standard medical libraries, copies of the papers would be greatly appreciated. Feel free to send us any additional material, including your thoughts on our task in memo or letter form. As you know, any material you send me will be put in the public access file. Responses would be appreciated as soon as possible, but no later than Friday, 5 May 2000.

Thank you for your consideration of this request.

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